

**TDMS No.** 20310 - 03

**Test Type:** 26-39 WEEKS

**Route:** GAVAGE

**Species/Strain:** MICE/C3B6F1-+/Trp53(tm1Brd)

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

AZT+3TC combination

**CAS Number:** AZT3TCCOMBO

**Date Report Requested:** 05/04/2010

**Time Report Requested:** 12:30:53

**First Dose M/F:** 12/22/06 / NA

**Lab:** NCTR

**C Number:** C20310B

**Lock Date:** 04/20/2010

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** ALL

**Removal Date Range:** ALL

**Treatment Groups:** Include ALL

**Study Gender:** Male

**TDMSE Version:** 2.2.0

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
<b>Disposition Summary</b>						
Animals Initially In Study	25	25	25	26	25	25
Early Deaths						
Moribund Sacrifice	1	2			1	
Natural Death	1	1	1	4		
Survivors						
Moribund Sacrifice	1	2			2	
Natural Death	2	2	1		1	1
Terminal Sacrifice	20	18	23	22	21	24
Animals Examined Microscopically	25	25	25	26	25	25

## ALIMENTARY SYSTEM

Intestine Large, Cecum	(22)	(22)	(24)	(22)	(24)	(24)
Intestine Large, Colon	(22)	(22)	(25)	(23)	(24)	(24)
Intestine Large, Rectum	(22)	(22)	(23)	(22)	(24)	(24)
Intestine Small, Duodenum	(23)	(22)	(23)	(22)	(24)	(24)
Ectopic Pancreas						
Intestine Small, Jejunum	(23)	(22)	(23)	(22)	(24)	(24)
Liver	(25)	(24)	(25)	(25)	(25)	(25)
Basophilic Focus			1 (4%)	1 (4%)	1 (4%)	
Hematopoietic Cell Proliferation	1 (4%)					1 (4%)
Infiltration Cellular, Lymphocyte				1 (4%)		1 (4%)
Inflammation, Suppurative						
Inflammation, Chronic Active			1 (4%)		1 (4%)	1 (4%)
Mixed Cell Focus			1 (4%)		1 (4%)	
Necrosis	1 (4%)		1 (4%)			1 (4%)
Tension Lipidosis		1 (4%)		1 (4%)	1 (4%)	2 (8%)
Vacuolization Cytoplasmic	19 (76%)	18 (75%)	20 (80%)	20 (80%)	21 (84%)	21 (84%)
Centrilobular, Degeneration	15 (60%)	16 (67%)	18 (72%)	17 (68%)	17 (68%)	20 (80%)
Mesentery	(3)	(0)	(0)	(1)	(2)	(1)
Inflammation, Chronic Active					1 (50%)	
Fat, Necrosis	1 (33%)				1 (50%)	
Pancreas	(24)	(23)	(25)	(25)	(24)	(25)
Cyst	1 (4%)	1 (4%)				

a - Number of animals examined microscopically at site and number of animals with lesion

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Hemorrhage					1 (4%)	
Infiltration Cellular, Lymphocyte					1 (4%)	2 (8%)
Acinus, Degeneration		1 (4%)	1 (4%)			
Salivary Glands	(25)	(23)	(25)	(25)	(24)	(25)
Infiltration Cellular, Lymphocyte	18 (72%)	12 (52%)	13 (52%)	18 (72%)	11 (46%)	14 (56%)
Stomach, Forestomach	(25)	(23)	(25)	(23)	(24)	(25)
Hyperkeratosis		1 (4%)				
Ulcer					1 (4%)	
Epithelium, Hyperplasia	1 (4%)				1 (4%)	
Stomach, Glandular	(23)	(22)	(24)	(22)	(24)	(24)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(25)	(24)	(25)	(25)	(24)	(25)
Heart	(25)	(25)	(25)	(25)	(24)	(25)
Mineralization						1 (4%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(25)	(24)	(25)	(25)	(23)	(25)
Accessory Adrenal Cortical Nodule	1 (4%)					
Cyst					1 (4%)	
Hypertrophy		1 (4%)				
Subcapsular, Hyperplasia	13 (52%)	12 (50%)	13 (52%)	7 (28%)	11 (48%)	14 (56%)
Adrenal Medulla	(25)	(23)	(25)	(23)	(21)	(25)
Islets, Pancreatic	(24)	(24)	(25)	(25)	(24)	(25)
Hyperplasia	13 (54%)	10 (42%)	15 (60%)	10 (40%)	14 (58%)	9 (36%)
Parathyroid Gland	(23)	(21)	(24)	(18)	(19)	(23)
Cyst			1 (4%)			
Pituitary Gland	(24)	(22)	(25)	(25)	(24)	(25)
Thyroid Gland	(25)	(23)	(25)	(23)	(23)	(25)
Ectopic Thymus	2 (8%)		1 (4%)			
Follicle, Degeneration						

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
GENERAL BODY SYSTEM						
Tissue NOS	(1)	(0)	(1)	(3)	(0)	(0)
Abscess				1 (33%)		
Abdominal, Fat, Necrosis			1 (100%)			
GENITAL SYSTEM						
Epididymis	(25)	(23)	(25)	(25)	(24)	(25)
Exfoliated Germ Cell		1 (4%)				
Hypospermia						
Inflammation, Chronic Active						
Preputial Gland	(25)	(24)	(25)	(25)	(24)	(25)
Cyst						1 (4%)
Infiltration Cellular, Lymphocyte			1 (4%)			1 (4%)
Infiltration Cellular, Plasma Cell		1 (4%)				
Inflammation, Suppurative		1 (4%)				
Inflammation, Chronic Active	1 (4%)	1 (4%)				
Keratin Cyst						1 (4%)
Acinus, Degeneration	3 (12%)	2 (8%)	3 (12%)	3 (12%)	1 (4%)	4 (16%)
Duct, Ectasia	3 (12%)	2 (8%)	2 (8%)	4 (16%)	1 (4%)	3 (12%)
Prostate	(25)	(23)	(25)	(25)	(24)	(25)
Infiltration Cellular, Lymphocyte			1 (4%)			
Inflammation, Suppurative			1 (4%)			
Seminal Vesicle	(25)	(23)	(24)	(25)	(24)	(25)
Testes	(25)	(24)	(24)	(25)	(24)	(25)
Seminiferous Tubule, Degeneration		1 (4%)	1 (4%)	2 (8%)		
HEMATOPOIETIC SYSTEM						
Bone Marrow	(23)	(24)	(24)	(25)	(24)	(25)
Hyperplasia	3 (13%)	3 (13%)	1 (4%)	2 (8%)	2 (8%)	2 (8%)
Lymph Node	(2)	(2)	(1)	(1)	(2)	(3)
Axillary, Hyperplasia, Lymphoid						1 (33%)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Lumbar, Hyperplasia, Lymphoid						1 (33%)
Mediastinal, Hyperplasia, Lymphoid	1 (50%)			1 (100%)		2 (67%)
Mediastinal, Infiltration Cellular, Plasma Cell						1 (33%)
Renal, Hyperplasia, Lymphoid						1 (33%)
Lymph Node, Mandibular	(25)	(23)	(25)	(25)	(24)	(25)
Hyperplasia, Lymphoid	2 (8%)	1 (4%)	2 (8%)	2 (8%)	2 (8%)	2 (8%)
Infiltration Cellular, Plasma Cell						
Lymph Node, Mesenteric	(24)	(23)	(25)	(25)	(24)	(25)
Congestion		1 (4%)				
Hyperplasia, Lymphoid	9 (38%)	5 (22%)	12 (48%)	11 (44%)	11 (46%)	10 (40%)
Infiltration Cellular, Plasma Cell			1 (4%)	2 (8%)	1 (4%)	1 (4%)
Infiltration Cellular, Polymorphonuclear						
Spleen	(25)	(23)	(24)	(25)	(24)	(25)
Congestion					1 (4%)	
Hematopoietic Cell Proliferation	7 (28%)	11 (48%)	4 (17%)	5 (20%)	11 (46%)	9 (36%)
Hyperplasia, Lymphoid	12 (48%)	14 (61%)	16 (67%)	18 (72%)	14 (58%)	15 (60%)
Thymus	(24)	(22)	(24)	(23)	(22)	(25)
Atrophy	2 (8%)	1 (5%)		1 (4%)	1 (5%)	1 (4%)
Cyst		1 (5%)				
Hyperplasia, Lymphoid	2 (8%)			1 (4%)	3 (14%)	3 (12%)
INTEGUMENTARY SYSTEM						
Skin	(25)	(25)	(25)	(25)	(24)	(25)
Cyst		1 (4%)				
Granuloma		1 (4%)				
Inflammation, Suppurative						
Epithelium, Hyperplasia						
MUSCULOSKELETAL SYSTEM						
Bone	(3)	(1)	(1)	(1)	(0)	(0)
Bone, Femur	(25)	(25)	(25)	(25)	(25)	(25)
Fibro-Osseous Lesion	1 (4%)					
Skeletal Muscle	(3)	(2)	(1)	(0)	(0)	(0)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
NERVOUS SYSTEM						
Brain, Brain Stem	(25)	(24)	(25)	(25)	(24)	(24)
Brain, Cerebellum	(25)	(24)	(25)	(25)	(24)	(24)
Compression			1 (4%)			
Hemorrhage		1 (4%)				
Brain, Cerebrum	(25)	(24)	(25)	(25)	(24)	(25)
Mineralization	2 (8%)	3 (13%)	4 (16%)	4 (16%)	2 (8%)	1 (4%)
Spinal Cord, Thoracic	(1)	(0)	(0)	(0)	(0)	(0)
Compression	1 (100%)					
RESPIRATORY SYSTEM						
Lung	(25)	(24)	(25)	(25)	(24)	(25)
Hemorrhage		1 (4%)			1 (4%)	1 (4%)
Infiltration Cellular, Histiocyte		1 (4%)	1 (4%)			
Inflammation, Chronic				1 (4%)		
Mineralization		1 (4%)		1 (4%)		
Alveolar Epithelium, Hyperplasia				1 (4%)		1 (4%)
Nose	(25)	(25)	(25)	(25)	(25)	(25)
Hyaline Droplet			1 (4%)		2 (8%)	3 (12%)
SPECIAL SENSES SYSTEM						
Eye	(22)	(22)	(23)	(23)	(24)	(24)
Inflammation, Chronic Active		1 (5%)				
Cornea, Ulcer		1 (5%)				
Harderian Gland	(25)	(22)	(25)	(25)	(24)	(25)
Infiltration Cellular, Lymphocyte	1 (4%)					1 (4%)
URINARY SYSTEM						

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Kidney	(25)	(24)	(25)	(25)	(24)	(25)
Casts Protein	3 (12%)	5 (21%)	6 (24%)	7 (28%)	8 (33%)	7 (28%)
Cyst						
Hemorrhage				1 (4%)		
Hydronephrosis	1 (4%)	8 (33%)	7 (28%)	5 (20%)	9 (38%)	13 (52%)
Infarct						
Infiltration Cellular, Lymphocyte	8 (32%)	2 (8%)	10 (40%)	6 (24%)	2 (8%)	9 (36%)
Metaplasia, Osseous			1 (4%)		1 (4%)	
Nephropathy	1 (4%)	1 (4%)	2 (8%)			
Renal Tubule, Regeneration			1 (4%)			
Transitional Epithelium, Hyperplasia			1 (4%)			
Urinary Bladder	(25)	(24)	(25)	(25)	(24)	(25)
Hemorrhage					1 (4%)	
Infiltration Cellular, Histiocyte				1 (4%)		
Infiltration Cellular, Lymphocyte	2 (8%)			2 (8%)	1 (4%)	1 (4%)
Lumen, Dilatation	1 (4%)	1 (4%)	1 (4%)	1 (4%)		

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
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## Disposition Summary

Animals Initially In Study	25	25
Early Deaths		
Moribund Sacrifice		
Natural Death		1
Survivors		
Moribund Sacrifice	1	1
Natural Death		
Terminal Sacrifice	24	23
Animals Examined Microscopically	23	24

## ALIMENTARY SYSTEM

Intestine Large, Cecum	(23)	(23)
Intestine Large, Colon	(23)	(23)
Intestine Large, Rectum	(23)	(23)
Intestine Small, Duodenum	(23)	(23)
Ectopic Pancreas		1 (4%)
Intestine Small, Jejunum	(23)	(23)
Liver	(23)	(23)
Basophilic Focus	2 (9%)	2 (9%)
Hematopoietic Cell Proliferation		
Infiltration Cellular, Lymphocyte	1 (4%)	
Inflammation, Suppurative	1 (4%)	
Inflammation, Chronic Active	1 (4%)	1 (4%)
Mixed Cell Focus		
Necrosis	1 (4%)	2 (9%)
Tension Lipidosis	2 (9%)	1 (4%)
Vacuolization Cytoplasmic	19 (83%)	20 (87%)
Centrilobular, Degeneration	18 (78%)	17 (74%)
Mesentery	(2)	(0)
Inflammation, Chronic Active		
Fat, Necrosis	2 (100%)	
Pancreas	(23)	(23)
Cyst		

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**C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE**

**AZT40,3TC25,NVP7**

**A60,3T37.5,N10.5**

Hemorrhage		
Infiltration Cellular, Lymphocyte		
Acinus, Degeneration	1 (4%)	
Salivary Glands	(23)	(23)
Infiltration Cellular, Lymphocyte	16 (70%)	16 (70%)
Stomach, Forestomach	(23)	(23)
Hyperkeratosis	1 (4%)	
Ulcer		
Epithelium, Hyperplasia		
Stomach, Glandular	(23)	(23)

**CARDIOVASCULAR SYSTEM**

Blood Vessel	(23)	(24)
Heart	(23)	(24)
Mineralization		

**ENDOCRINE SYSTEM**

Adrenal Cortex	(23)	(23)
Accessory Adrenal Cortical Nodule		1 (4%)
Cyst		
Hypertrophy	1 (4%)	2 (9%)
Subcapsular, Hyperplasia	11 (48%)	12 (52%)
Adrenal Medulla	(23)	(22)
Islets, Pancreatic	(23)	(23)
Hyperplasia	13 (57%)	6 (26%)
Parathyroid Gland	(23)	(23)
Cyst		
Pituitary Gland	(23)	(23)
Thyroid Gland	(23)	(23)
Ectopic Thymus		
Follicle, Degeneration		1 (4%)

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**AZT40,3TC25,NVP7**

**A60,3T37.5,N10.5**

**GENERAL BODY SYSTEM**

Tissue NOS	(0)	(0)
Abscess		
Abdominal, Fat, Necrosis		

**GENITAL SYSTEM**

Epididymis	(23)	(23)
Exfoliated Germ Cell		1 (4%)
Hypospermia		1 (4%)
Inflammation, Chronic Active	1 (4%)	
Preputial Gland	(23)	(23)
Cyst		
Infiltration Cellular, Lymphocyte		
Infiltration Cellular, Plasma Cell		
Inflammation, Suppurative	1 (4%)	
Inflammation, Chronic Active	1 (4%)	
Keratin Cyst		
Acinus, Degeneration	7 (30%)	5 (22%)
Duct, Ectasia	5 (22%)	5 (22%)
Prostate	(23)	(23)
Infiltration Cellular, Lymphocyte		
Inflammation, Suppurative	1 (4%)	
Seminal Vesicle	(23)	(23)
Testes	(23)	(23)
Seminiferous Tubule, Degeneration	1 (4%)	1 (4%)

**HEMATOPOIETIC SYSTEM**

Bone Marrow	(23)	(23)
Hyperplasia	4 (17%)	
Lymph Node	(1)	(1)
Axillary, Hyperplasia, Lymphoid		

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**AZT40,3TC25,NVP7**

**A60,3T37.5,N10.5**

Lumbar, Hyperplasia, Lymphoid		
Mediastinal, Hyperplasia, Lymphoid		
Mediastinal, Infiltration Cellular, Plasma Cell		
Renal, Hyperplasia, Lymphoid		
Lymph Node, Mandibular	(23)	(23)
Hyperplasia, Lymphoid	4 (17%)	5 (22%)
Infiltration Cellular, Plasma Cell	1 (4%)	
Lymph Node, Mesenteric	(23)	(23)
Congestion		
Hyperplasia, Lymphoid	5 (22%)	9 (39%)
Infiltration Cellular, Plasma Cell	1 (4%)	
Infiltration Cellular, Polymorphonuclear	1 (4%)	
Spleen	(23)	(23)
Congestion		
Hematopoietic Cell Proliferation	6 (26%)	6 (26%)
Hyperplasia, Lymphoid	13 (57%)	12 (52%)
Thymus	(20)	(20)
Atrophy		1 (5%)
Cyst		
Hyperplasia, Lymphoid	1 (5%)	1 (5%)

**INTEGUMENTARY SYSTEM**

Skin	(23)	(24)
Cyst		
Granuloma		
Inflammation, Suppurative		1 (4%)
Epithelium, Hyperplasia		1 (4%)

**MUSCULOSKELETAL SYSTEM**

Bone	(1)	(1)
Bone, Femur	(23)	(24)
Fibro-Osseous Lesion	1 (4%)	
Skeletal Muscle	(0)	(0)

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**AZT40,3TC25,NVP7**

**A60,3T37.5,N10.5**

**NERVOUS SYSTEM**

Brain, Brain Stem	(23)	(23)
Brain, Cerebellum	(23)	(23)
Compression		
Hemorrhage		
Brain, Cerebrum	(23)	(23)
Mineralization	3 (13%)	1 (4%)
Spinal Cord, Thoracic	(0)	(0)
Compression		

**RESPIRATORY SYSTEM**

Lung	(23)	(23)
Hemorrhage		
Infiltration Cellular, Histiocyte		
Inflammation, Chronic		
Mineralization		
Alveolar Epithelium, Hyperplasia		1 (4%)
Nose	(23)	(24)
Hyaline Droplet	2 (9%)	

**SPECIAL SENSES SYSTEM**

Eye	(23)	(23)
Inflammation, Chronic Active		
Cornea, Ulcer		
Harderian Gland	(23)	(23)
Infiltration Cellular, Lymphocyte	1 (4%)	

**URINARY SYSTEM**

a - Number of animals examined microscopically at site and number of animals with lesion

**TDMS No.** 20310 - 03

**Test Type:** 26-39 WEEKS

**Route:** GAVAGE

**Species/Strain:** MICE/C3B6F1-+/Trp53(tm1Brd)

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

AZT+3TC combination

**CAS Number:** AZT3TCCOMBO

**Date Report Requested:** 05/04/2010

**Time Report Requested:** 12:30:53

**First Dose M/F:** 12/22/06 / NA

**Lab:** NCTR

**C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE**

**AZT40,3TC25,NVP7**

**A60,3T37.5,N10.5**

Kidney	(23)	(23)
Casts Protein	7 (30%)	10 (43%)
Cyst	1 (4%)	
Hemorrhage		
Hydronephrosis	5 (22%)	12 (52%)
Infarct	1 (4%)	
Infiltration Cellular, Lymphocyte	9 (39%)	7 (30%)
Metaplasia, Osseous		
Nephropathy		1 (4%)
Renal Tubule, Regeneration		
Transitional Epithelium, Hyperplasia		
Urinary Bladder	(23)	(23)
Hemorrhage		
Infiltration Cellular, Histiocyte		
Infiltration Cellular, Lymphocyte	1 (4%)	1 (4%)
Lumen, Dilatation		

\*\*\* END OF REPORT \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion